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THROUGH THE THICKET AND ACROSS THE DIVIDE: SUCCESSFULLY NAVIGATING THE REGULATORY LANDSCAPE IN LIFE SCIENCES RESEARCH

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Abstract: This chapter addresses the considerable problems that arise within and between regulatory regimes when there is a failure to implement intelligent design that is responsive to the realities of life sciences research. We argue that a root cause of these problems is the dichotomization of regulatory regimes as between tissue and data and the creation of a *non-nexus* between bodies of knowledge and legal responses to technological developments. The result is a regulatory thicket and a net failure to deliver effective, efficient and proportionate regimes. Taking the UK and European context as its example, this chapter argues for a collapse in the distinction between tissue and data and for more fluid and reflexive governance systems that not only embody interdisciplinary intelligent design but are also constructed around legal architectures that are responsive to changing scientific and social mores. This requires less, not more, proscription from law.

INTRODUCTION

The metaphor of the ‘regulatory landscape’ may be over-used, but its utility ensures its continuation. The metaphor is particularly apt for lawyers (working around the life sciences) because much of the responsibility for navigating the landscape is theirs. Within this landscape, law is often characterised – or caricatured – as both creator of problems and bringer of solutions. We argue that both accounts are true, but only in half-measure. While it is often said that law struggles to keep up with rapid advances in the life sciences, we focus on a particular aspect of this struggle, viz, it is not due to an absence of law but rather to the significant (and ever-expanding) space that law has come to occupy. The result is that law is often seen as a ‘thicket’: a complex, fragmented, and cumulative collection of instruments, institutions, and mechanisms that requires ever greater knowledge, time and capital to navigate, thereby imposing disproportionate costs on actors and requiring inordinate amounts of effort to move through.

We posit that a root cause of many of the problems associated with the regulatory thicket is the piecemeal and reactive ways in which law has emerged; it has grown rapidly under the guidance of those largely uninformed about the workings and trajectories of modern life sciences and has tended to operate in a compartmentalised/atomised fashion – focusing on particular *objects* of regulatory concern, and building frameworks around those objects, rather than taking the time and adopting a broader perspective to view technological trajectories holistically (cf, Metzler and Webster, 2011). Two particular regulatory objects have caught regulators’ attention: human tissue; and personal

data. In scientific terms these might be seen as connected and indistinguishable in relation to their potential and value as sources of new knowledge, but in legal terms they have become subject to vast and disconnected structures of control involving local, national and international authorities and instruments, and a plethora of judicial decisions on how their collection, storage and use does or does not impinge on the legal rights of those from whom they are derived. In short, regulatory systems have grown up around tissue and data with little, if any, consideration of how these regulatory objects relate to each other or, indeed, to the interests that the systems are designed to protect.

This chapter argues that the unanticipated and worrying consequence of these processes is a net failure to deliver regulatory systems that work to protect citizens' rights and to promote scientific development (where such is warranted). The undesirable result is that, despite the complex of regulatory rules and standards, the risks regulated for persist, sometimes living in the many gaps between regulatory instruments, and new ones are generated. Focusing on the life sciences, and more specifically the (controversial) storage and use of newborn bloodspot collections, we explore the problem of unintelligent regulatory design. We advocate a re-visioning of design: one that is driven by appropriate objects of attention, that is proportionate, reflexive, value-based and interest-achieving, and that does not attempt to impose anticipatory control of science trajectories but rather provides an adaptive *regulatory continuum*.

'THICKETS' AND 'DIVIDES' IN LIFE SCIENCE REGULATION

An examination of life sciences regulation discloses a general drift toward a 'decentred' approach (Black, 2001) whereby control/influence is exercised by a diffuse collection of actors which includes but goes beyond the state. In short, despite injunctions to focus regulation, particularly state efforts, on specific problems or objectives (Sparrow, 2000) and to ensure that efforts are 'responsive' (Baldwin, Cave, Lodge, 2012), the life sciences are characterised by multiple authority-wielding actors bringing to bear different and often conflicting interests and values from perspectives that are frequently narrow, all of which get captured in elements of the landscape. Moreover, actors call on others to intervene (or contribute to the landscape) despite not fully appreciating the propriety of what might be delivered. The law is frequently called upon to so intervene, and it has frequently done so; regimes governing the life sciences have burgeoned in the last half century. The legal landscape relevant to human tissue is a good illustration of this growth.

The *Human Tissue Act 1961* was 2.5 pages long and consisted of four sections. Its successor, the *Human Tissue Act 2004* (HRA 2004), has 61 sections (and 7 Schedules) and is 25 times longer than the original Act. It established a regulatory system, including the establishment of a statutory governing authority, the regulation of consent, storage and use, provisions on property, and the articulation of criminal offences. Moreover, for those conducting research on human material, the HTA 2004 is but one of many legislative landmarks that sit at the centre of a mesmerising landscape of legislative provisions, professional guidelines, and ethical approval mechanisms. Those dealing with human

reproductive material must navigate an entirely different legal landscape as articulated by the *Human Fertilisation and Embryology Act 2008* (HFEA 2008). This erects separate institutional and licensing arrangements despite the fact that, in practice, the distinction between reproductive/non-reproductive materials is not always clear.

Further, research in the life sciences must begin and end with willing participants whose personal data will inform to greater and lesser extents the establishment of basic research resources or, indeed, downstream research and products. The processing of personal data is governed by a European regime which in the UK is implemented by the *Data Protection Act 1998* (DPA 1998). All forms of handling and storing personal data are caught by its provisions. While anonymised data are not caught by the regime, the processes of securing 'adequately anonymised' data are elusive, and all handling of data up to and including anonymisation are covered by the DPA 1998.

Various additional science-dependent considerations complicate the picture further. Research that is conducted with a view to delivering products or benefits to the market must satisfy various regimes as governed by the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA). These can include conformity with the European Clinical Trials Directive (designed to establish safety and efficacy in medicinal products) and/or the medical devices regimes (designed to test safety and performance). At various junctures, researchers will encounter and have to satisfy research ethics committees – of which there can be many, arising within each of the above regimes – as well as local, more ad hoc arrangements that are driven by particular concerns (e.g., the protection of research participants' privacy). Finally, all of these regimes and the conduct that they are designed to regulate must be in conformity with human rights. In Europe, this regime stems from the Council of Europe's Convention on Human Rights (1950), as incorporated into UK law by the *Human Rights Act 1998*.

The increasingly expansive nature of law's participation in (if not dominion over) life sciences regulation has not been tempered by a well-informed and proportionate approach. Accordingly, the problem of the regulatory thicket is well-recognised in the research community, which has frequently lamented the regulatory burden under which it labours. Giving evidence to the House of Lords Science and Technology Committee in 2009, Andrew Morris noted:

The Department of Health guidance suggests that this domain is affected by 43 relevant pieces of legislation. There were 12 sets of relevant standards and eight professional codes of conduct. What this has bred is a culture of caution, confusion, uncertainty and inconsistency. (HL, para 6.15)

The Academy of Medical Sciences (AMS) has twice reported on the issue, first in the context of using health information in medical research (AMS, 2006) and then in a wider call for more proportionate governance regimes (AMS, 2011). A common theme in these analyses is that confusion about law and the constraints and flexibilities that it allows is a recurring problem; a further cross-cutting

theme is the call for a shift in regulatory culture as part of the solution. This has resonance with the recommendations of the Data Sharing Review (2008), which reported that:

We have found that in the vast majority of cases, the law itself does not provide a barrier to the sharing of personal data. However, the complexity of the law, amplified by a plethora of guidance, leaves those who may wish to share data in a fog of confusion. (Thomas and Walport, 2008, Foreword)

It was addressing the information governance environment only; in cases where downstream market considerations come into play, the complexities multiply.

To demonstrate how these thickets can evolve, and to exemplify the deeply unhelpful divides that are erected/perpetuated, we consider one particular undertaking: the ambition to conduct research using newborn bloodspot collections, or so-called 'Guthrie cards'. Newborn screening programmes began in many western countries in the 1960s. They involve a heel-prick sample of blood from the infant that is retained on manual cards. Blood samples are initially taken in the health interests of the infant to diagnose and treat conditions that can be detected and eradicated or effectively managed at this early stage of life (e.g. phenylketonuria (PKU) or hypothyroidism). It was common to retain these cards, however, and their value has grown over the decades both with advances in genetic analysis and with the prospect of effective linkage to medical and other records (Couzin-Frankel, 2009).

Perhaps unsurprisingly, the nature and balance of the interests implicated have changed, as have the social attitudes and the legal regimes involved. Whereas the idea of asking for consent was anathema in the 1960s, consent has ascended to a principal role in patient management and research regulation (Laurie, 2002). Equally, the advent of tissue and data protection regimes has changed the calculus (Lewis et al, 2011; Hu, 2012); they raise important questions about the legal status of these collections, which contain both tangible (blood spots as tissue) and intangible (personal data) elements, and which have been recognised as de facto state-held DNA databases (Nuffield Council on Bioethics, 2007).

A failure to engage families and publics around the existence and possible uses of such resources has resulted in numerous high-profile destructions of entire collections. For example, in *Beleno v Texas Dept. of State Health Services* (2009), the failure to obtain parental consent for the retention and use of blood spots was raised as an infringement of Constitutional rights (Drabiak-Syed, 2011). As part of the out-of-court settlement, the Department of Health ordered that four million samples be destroyed. In Canada, *LD and ED (Guardian Ad Litem) v British Columbia Women's Hospital and Health Centre and British Columbia Children's Hospital* (2010), was initiated for breach of privacy, and most recently the Irish Department of Health and Health Service Executive have announced plans to destroy its collection unless appropriate consent for retention is obtained (Irish Times, 7 March 2013). The argument underlying all of these cases is that data protection law does not permit retention and use without this specific consent.

There have, of course, been attempts to address the challenges that new uses and changing regulatory regimes create.¹ But these initiatives all seem to face a common problem alluded to above: existing legal regimes have developed in a sector-specific manner. Thus, data protection and the common law of confidentiality govern data sharing and linkage, while the HTA 2004 and common law developments on property in the body dominate tissue research (Harmon and Laurie, 2010). These legally-created and embedded artificial distinctions are not only unhelpful but potentially obstructive to the core interests they purport to protect.

Looking beyond law, human geographer Bronwyn Parry has argued that we need to collapse distinctions in order to explore questions about who controls 'bio-informational' transactions in the global economy (Parry, 2004). While Parry's concern is to understand the downstream intellectual property and benefit-sharing regulations that apply once transformations have taken place, we are more concerned with the logically prior and upstream question of regulating the 'raw' materials and data *before* any commercial value is realised. The perspectives are inherently connected, however, because ultimately we must all consider the importance of a coherent regulatory continuum from basic research to delivery of benefit. Having said that, the upstream considerations are particularly important for two reasons. First, complete 'decontextualisation' of the materials and data has not yet taken place in that connections to persons remain, necessitating regulatory regimes that avert to the protection of their rights and interests in the handling of said materials. Second, serious limits or outright failures in regulatory regimes in the early stages of research and technological development will thwart efforts to realise any downstream benefits.

A well-designed regulatory continuum can help facilitate the translation of knowledge to product but bridging the tissue/data divide is critical. At present, legal frameworks and those working within them interact insufficiently and fail to see the bigger picture despite literatures on data-sharing and tissue-use being replete with common governance challenges (e.g., propriety and expectations around consent, overly complex legal provisions and disproportionate regulatory burdens, concerns around public and research participant trust, and conflicting ambitions for public and participant engagement).

THE WIDENING 'DIVIDE' IN DATA AND TISSUE

¹ For example, the Health Research Authority was created in 2011 with a specific remit to: "create a unified approval process and to promote proportionate standards for compliance and inspection within a consistent national system of research governance" (HRA website). We have also developed a regime in the Wellcome Trust Scottish Health Informatics Programme that adopts a principles-based approach to the sharing and linkage of health-related data and that delivers a proportionate approval scheme that matches applications to link and share data to appropriate governance pathways based on a risk-based approach (Laurie and Sethi, 2013).

A crucial step in delivering appropriate and proportionate governance is the vertical and horizontal trimming of the regulatory thicket. The current data/tissue regulatory divide is deeply unhelpful; not only can it lead to further cross-sector regulatory burden when the same artefact is caught by different regimes, but it can also lead to regulatory responses that are almost wholly divorced from the technological and scientific realities of dealing with tissues and data. From a biomedical perspective, tissue and data are simply different points on a continuum; tissue is less valuable for its tangible qualities than for the precious data it yields. Equally, data is important not necessarily in and of itself, but because of the aggregate value that derives turning raw data into *information*. Law fails completely to appreciate this relative value and its implications.

Consider the example of the European data protection regime, currently under review. The focus for regulatory attention is the processing of ‘personal data’. This is defined as “data which relate to a living individual who can be identified—(a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller” (DPA 1998, s1(1)(e)). The details of the regulatory requirements are immaterial for present purposes; rather, three observations can be made.

First, the regime is premised on a semblance of continuing connection between data being processed and the person to whom they relate. This is so irrespective of the nature or degree of any risks (such as to privacy) to the said person; moreover, it is blind to the motive or interest of the data controller. In essence, it treats the snooper in the same way as the researcher who is only interested in the aggregate value of information about a cohort of persons rather than any one individual (although see the limited provisions of the ‘research exemption’ discussed below).

Second, the definitions imply that if individuals are not identifiable from the data then the regime does not apply (i.e., anonymised data are not caught). This, however, raises two questions: What level of anonymisation is sufficient, given that such processes are more art than science? What is the position if identifiable data *are* required for the scientific robustness of research? This is an on-going issue and the subject of considerable uncertainty and variation in practice. It has most recently been addressed in the UK by a Code of Practice from the Information Commissioner’s Office (ICO, 2011). The Code provides recommendations to minimise risks but leaves a margin of appreciation with respect to what counts as *effective* anonymisation. It does not have legal force and its reach is limited to practices within the UK. In one key respect, however, it provides assistance in conducting risk assessments with respect to anonymisation practices: it recommends considering privacy threats relative to the ‘motivated intruder’, that is, what would be the likelihood of success if someone sought to use anonymised data to re-identify individuals when they were a reasonably competent actor with access to public resources and who would make enquiries of third parties who could provide additional information? The test does not assume specialised knowledge or skills (e.g., hackers), nor access to specialist equipment, nor resort to criminality. Thus, the

threshold is set mid-way between the 'relatively inexpert' member of the public and the 'skilled specialist with prior knowledge'. The test operates by way of a benchmark against which data controllers can test the robustness of their anonymisation practices, noting importantly that motives, threats and risks can change over time and therefore policies and practices must be kept under regular review – adding to the administrative and regulatory burden of policing the use of anonymised data.

Third, as to research uses of identifiable data, the data protection regime provides a limited research exemption that can apply to data obtained for one purpose when later used for a research purpose so long as two crucial criteria are met:

- (i)...the data must not be processed to support measures or decisions with respect to particular individuals, and (ii) the data must not be processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject. (DPA 1998, s. 33).

Effectively anonymised data clearly meet these requirements. As to identifiable data, the justification must be made. If applicable, the consequence is that data can be retained indefinitely (normally data must be destroyed after original purposes for processing are met), and data subjects need not be granted access to their data (otherwise a norm in the regulations) *so long as* research results are not published in an identifiable form. This is an attempt to relieve the regulatory burden of managing access requests, but this has been undermined by the fact that the Code suggests that granting such access is good practice (2012, p. 46). Moreover, the reduction in burden might be slight because while consent to research uses is not mandated, data subjects must still have adequate notice of the fact that data are being used for research. And if consent is not obtained and research data cannot be published in an effectively anonymised form, then subject access must be granted and the researcher is exposed to an action for breach of data protection (unless it could be shown that there was no alternative but to publish the results in an identifiable form).

The result is that research involving personal data continues to be constrained by the 'consent or anonymise' paradigm that has been so heavily criticised by the research community (AMS, 2006). This might be compounded further if current proposals to develop a European Data Protection Regulation are adopted in their current form. A January 2013 report from a European Parliament Committee advocated that research involving health data should only be conducted with data subject consent, which should be "freely-given, specific, informed and explicit" (EP, 2013, p.198). If this is not possible then research would only be permitted if it served "an exceptionally high public interest" and data must then be "anonymised or at least pseudonymised using the highest technical standards" (EP, 2013, p.198). This trajectory for regulation is disconcerting because it suggests a widening, not a closing, of the gap between law and scientific practice contrary to accumulated experience. The slow pace and political charge of European legislative change are notorious, and the time to worry for data

protection and health-related research has not yet come, but this phenomenon speaks to the deeper issues that concern us in this chapter.

A further example from data protection – this time from the European Court of Human Rights (ECtHR) – indicates that a proportionate and common-sense approach is not prevailing, making the imperative for change all the stronger. *S and Marper v United Kingdom* (2008) concerned the lawfulness of the blanket policy in England & Wales to retain indefinitely and without consent DNA profiles and samples taken from persons arrested for (but never convicted of) criminal offences, however minor. It was held that such an indiscriminate policy was a breach of human rights that could not be justified. In the wake of the decision, the law was changed to embody a more proportionate approach involving time limits for retention (3 years usually), but with the possibility of longer retention depending on whether there was a prior record of serious offending and/or the seriousness of the instant offence (*Protection of Freedoms Act 2012*, Chapter 1). The reforms will result in around 1 million samples being destroyed, to be completed by May 2013 (Hansard, 2012).

The significance of *Marper* lies in two key findings of the ECtHR. First, mere retention of DNA – even without use – is an interference with the human right to respect for private life because of the possible implications that future uses can have for individuals (*Marper*, paras 67-77). This can be justified in the public interest so long as any interference meets a social need and is necessary and proportionate. Second, the samples, DNA profiles and any information derived from them constitute “personal data” within the data protection regime (*Marper*, para 67), a fact previously accepted by the UK government. These findings can be contrasted with 2007 Opinion of the Article 29 Working Party which exists as an independent advisory body on matters of European data protection:

Human tissue samples (like a blood sample) are themselves sources out of which biometric data are extracted, but they are not biometric data themselves (as for instance a pattern for fingerprints is biometric data, but the finger itself is not). Therefore the extraction of information from the samples is collection of personal data, to which the rules of the Directive apply. The collection, storage and use of tissue samples themselves may be subject to separate sets of rules. (Article 29 Working Party, 2007, p.9).

Herein lies the rub. One European body suggests that DNA samples are ‘personal data’ in their own right while another advises contrarily and claims that separate rules might apply. Consequently, there is legal uncertainty about the status of tissue samples with respect to whether they are caught by the data protection regimes while, at the same time, there are additional legal regimes being applied to human tissue alone. The implications are potentially profound. On either perspective we have growth of the regulatory thicket. Either a cautious approach will be adopted to the regulation of health-research involving data and tissues – in which case both regimes will be considered to apply – or the divide between data and tissues will be considered self-evident, in which case separate regimes will evolve that necessarily have overlapping effect.

We do not argue that data protection ought or ought not to apply to human tissues. Rather, we make a plea to develop and implement regulatory regimes that adopt a functional approach both with respect to the protection of core human rights and interests as well as the likely cumulative effect of their operation on the scientific endeavour. From a scientific perspective the data/tissue dichotomy is a false one. The distinction can be collapsed with little consequence. Can we achieve this view in law?

COLLAPSING THE 'DIVIDE' BETWEEN DATA AND TISSUE

Although the regulatory objects in these diverse regimes are data and tissue, the core concern of the law – quite rightly – is the perceived link to the individual and the protection of his or her rights and interests. Seen in this way, regulatory regimes can be found to have much in common. For example, each regime (tissue and data) is far less onerous if anonymisation is achievable (i.e., if the link to the individual is broken). When the link remains, there is a tendency to place the individual at the centre of regulatory propriety (i.e., individual consent is needed to legitimise dealings with the tissue and data). We have argued elsewhere that consent is neither necessary nor sufficient to protect individual concerns in the health research context (Laurie and Postan, 2012).

Moreover, the tendency in law to fix the 'consent moment' by the use of the now ubiquitous consent form is dangerous and limiting for many reasons, not least that it can only represent a snapshot of expectations and responsibilities. This ignores the fact that expectations and responsibilities can and will change over time. To the extent that prior consent says anything about an individual's future interests, it can have an ossifying effect on their protection, foregoing the opportunity to develop dialogue and partnership with research participants. Where consent has a role to play, then, it should be seen as a continuing process necessitating genuine interaction throughout the life of the project (Laurie and Postan, 2012).

As we argued above, though, consent is not always possible or appropriate. Accordingly, it is here that law probably fails most to take a proportionate view of what is at stake. If the function of law is to protect core rights and interests, then what *are* the legitimate residual interests that individuals have in their tissue and data once these find their way into a research setting? Privacy is undoubtedly a key concern, yet many concerns around privacy can be addressed through adequate security and access arrangements. Such measures can reduce the risks involved, as well as serve to screen for future inappropriate motives in access and use.

Notwithstanding these technical responses/solutions, some have argued that the importance given to individual autonomy should deliver a degree of continuing control over data and samples to originators of that tissue or data (Beyleveld and Histed, 2000). For example, one might find it objectionable if one's tissue or data were used to further research objectives that one finds offensive or immoral. While the existence of affront might be real, it is not obvious what the legitimate *legal* interest is that would be compromised. It is not privacy, which is about

intrusion into a state of separateness from others (Laurie, 2002), nor is it bodily integrity since samples are no longer part of the individual and the data never were. But the control metaphor looms large because we tend to talk about both samples and data as if they were extensions of ourselves. The trend toward autonomy reinforce this, most particularly in the fetishisation of consent; moreover, there are some judicial mutterings about property in the body which reinforce these intuitional perspectives (Harmon and Laurie, 2010).

Where does this leave law? The consent-based approach to research regulation has strength in its focus on the importance of the individual and in its strong suggestion of an element of control. There is, in fact, an elegant simplicity in such an approach. But much is lost as a result. First, the power that consent provides is largely the power to say 'No' (i.e., to refuse). Second, it is not clear that consent can ever operate alone or in a primary role to protect research participants' interests, and the role of consumer protection laws is a helpful analogy here. Third, the simplicity of the solution leads us to ignore/overlook much that is at stake especially in terms of the overall interests in play.

We contend that the appropriate regulatory ambition for law is to *correctly* identify and facilitate the core interests and values at stake, not just private interests (of research participants) but also public interests (such as promoting scientifically sound and ethically robust research). This demands a clearer and more sustained commitment to the wider range of underlying values that promote this broad spectrum of public and private interests (Harmon, 2010; Harmon, 2011; Laurie, Harmon, Arzuaga, 2012; Nuffield Council, 2012). Here, an important but often un-vindicated value is that of solidarity, which encourages us to adopt a more social or communitarian stance and to consider what duties might flow from the individual in support of valuable undertakings aimed at the collective (Harmon, 2006; Nuffield Council, 2011).

Accordingly, we advocate a functional approach to regulation in this area that is constructed around both the nature and scope of interests at stake, and which is calibrated by a consideration of the relative risks to said interests. For example, if the core continuing interest that individuals have in research using tissue or data derived from them is privacy, then an appropriate regulatory response would be to address security and access. If research can be demonstrated to have a reasonable prospect of promoting public interests it should be supported. Yet, the trend towards the non-negotiability of consent militates against this. Ironically, it does not guarantee that core interests will be better protected and it runs the considerable risk that public interests will be thwarted. This is not to suggest that consent never has a role to play. Rather, we propose that consent must be deployed as one in a set of regulatory options relating to the range of interests and objectives at stake.² Paying due attention to the importance that many people place on consent is an important element in fostering trust in research. Equally, however, trust in that enterprise is dependent on the research

² We have advocated this elsewhere in the context of data linkage governance (Laurie and Sethi, 2013).

delivering on its promises, and this can and does take commitment and investment over time.

Given this reality, governance regimes must be adaptive and reflexive; that is, capable of picking up on signals about shifting parameters, including participant expectations and scientific possibilities, and responding to these quickly and effectively (Laurie, 2011; Harmon, Laurie and Haddow, 2013). A reflexive system of governance is based on constant interaction between stakeholders, including participants and publics, and, importantly, it is not entirely dependent on law. At best, law can provide structural architectures within which reflexive governance can be delivered, but it is a crude tool to provide what is needed on the ground and on a case-by-case basis (Laurie, 2013). It further suggests the need for multi-disciplinary design in regulatory regimes, at both the conceptual and the operational stages. A first step in this is collapsing any false distinctions such as that between tissue and data in health-related research.

CROSSING THE 'DIVIDE': NEWBORN SCREENING PROGRAMMES REDUX

As indicated above, Guthrie card collections are a prime example of the challenges that face contemporary biomedical research. The hurdles to (research) success are compounded by the legal regimes that have grown up in an ad hoc manner in the decades since their establishment. While some have turned their attention to the need for appropriate guidance (Botkin et al, 2013; Chrysler et al, 2011), there has been far less consideration of the lessons to be learned for law. The long-term nature of the collection poses considerable dilemmas about whether and how it is appropriate or possible to impose contemporary governance requirements – such as consent – on collections that were established at a very different time (and in this regard we note the literature on museums and the politics of display: Lohman and Goodnow, 2006).

The value of the resource has also changed over time and will continue to do so, as will the nature of any interests people have in samples and data, facts which also complicate their appropriate regulation. Arguably, with respect to the tissue originators, direct health interests diminish and are replaced by core privacy interests. On our analysis, if the research value of the collection can be demonstrated and if adequate security and access provisions are put in place, this interest is met. In such a case, must consent still be sought (assuming it is at all practicable to do so)? There is no reason to suggest that consent from parents of present and future newborns should not be sought for inclusion in the resource since this is the dominant contemporary ethical paradigm. But whether retrospective consent should be sought or even contemplated is another matter. The logistics aside, we posit that on-going governance of such resources need not and should not place consent as its central focus.

And what is the legal status of such collections in light of the argument above? The decision in *Marper* suggests that data protection applies, but the tangible nature of the collection will also be caught by tissue legislation where this exists. Accordingly, in England and Wales both the DPA 1998 and the HTA 2004 must be observed. In Scotland, the collection of four million samples is treated as part

of the medical record (i.e., for the informational value that it represents). Arguably, there is no need for an additional layer of legal regulation simply because tangible cards/spots are involved (and we acknowledge the literature on materiality as exemplified by Faulkner, Lange, Lawless, 2012, and the special issue it introduces). To require consent represents an example of disproportionate governance relative to the risks and interests at stake. Far more importantly for the future and for the effective protection and promotion of both private and public interests, is the need for dynamic governance arrangements that both engage publics about the existence and value of such resources and deliver transparent and adaptive mechanisms for their management (Douglas et al, 2012). Arguments for the primacy of consent are not self-evident, either practically (given the scale and age of the resources) or as a matter of principle (it is unlikely to deliver a balance of all interests).

As a robust alternative to consent, there is the role of independent oversight bodies (Rothwell et al, 2011), perhaps with lay representation as appropriate (albeit this raises important questions about what is meant by both 'lay' and appropriateness of representation). Denmark and other European countries have adopted this model, charging a suitably-constituted body with the stewardship of the resource (Nørgaard-Pedersen and Hougaard, 2007). We support such an approach and suggest further that central to its operation must be a commitment to the twin principles of openness and reflexivity.

CONCLUSION

After much deliberation, the UK government announced that it will not abolish the Human Tissue Authority or the Human Fertilisation and Embryo Authority as had been proposed. Rather, it will conduct bespoke reviews of the functions of these regulatory entities with a view to reducing regulatory burden (Department of Health, 2013, para 69). This is only the UK context and we must take into account European and international regulatory pressures; yet, we strongly suggest that any such reviews in the near or longer-term future must consider both the vertical and horizontal branches of the regulatory thicket. We advocate an approach that is cognizant of the full range of underlying values and interests at stake in modern health research and which embraces and reflects key features that deliver both responsiveness and proportionality in regulation. Legal architectures that embody a command and control approach are unlikely to reflect these dimensions. This is a plea to recognise the limits of law and a call to deliver intelligent regulatory design at the nexus of science and law that reflects scientific realities and changing understandings of what counts as social goods.

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